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PART II:

ENVIRONMENTAL PROTECTION AGENCY

■

DRINKING WATER REGULATIONS

Radionuclides

Title 40—Protection of Environment

CHAPTER 1—ENVIRONMENTAL PROTECTION AGENCY

[FRL 552-2]

PART 141—INTERIM PRIMARY DRINKING WATER REGULATIONS

Promulgation of Regulations on Radionuclides

On August 14, 1975, the Environmental Protection Agency (EPA) proposed national interim primary drinking water regulations for radioactivity pursuant to sections 1412, 1445, and 1450 of the Public Health Service Act ("the Act"), as amended by the Safe Drinking Water Act, Pub. L. 93-523, 40 FR 34324. Numerous written comments on the proposed regulations were received, and a public hearing was held in Washington on September 10, 1975.

The regulations for radioactivity are hereby promulgated in final form. A number of changes have been made in the proposed regulations in response to comments received. These changes represent efforts to clarify what are necessarily technical and complex provisions and to make monitoring requirements more realistic. The proposed maximum contaminant levels for radionuclides have been retained as proposed.

The comments received on the proposed regulations and EPA's response to those comments are discussed in detail in Appendix A. The promulgated radionuclides regulations and Appendix A should be read in the context of the national interim primary drinking water regulations as a whole. The regulations concerning microbiological, chemical and physical maximum contaminant levels, and related regulations dealing with public notification of violations and reports and record-keeping by public water systems, were promulgated on December 24, 1975, 40 FR 59566.

The balance of this preamble discusses briefly the five major issues highlighted in the preamble to the proposed radionuclides regulations, and lists in summary form the changes made in the proposed regulations.

The preamble of the proposed regulations listed five issues on which comment was particularly requested:

1. The number and location of the public water systems impacted by the proposed maximum contaminant levels for radionuclides.

2. The number and location of water supplies requiring radium analysis at the proposed 2 pCi/liter gross-alpha-particle-activity screening level.

3. The estimated preliminary assessments of the costs and technology for radium removal.

4. The validity and appropriateness of an aggregate dose method for setting maximum contaminant levels.

5. The acceptability of a maximum contaminant level for radium of 5 pCi/liter as opposed to a higher or lower level.

Public Water Systems Impacted: Little significant information was provided with respect to the number of community water systems that may exceed the proposed maximum contaminant levels. The State of Texas did report that 15 community water systems in that State would exceed the 5 pCi limit for radium: EPA estimated in the preamble to the proposed regulations that a total of approximately 500 of the Nation's community water systems would exceed the proposed radium limit. It is likely that relatively few community water systems currently exceed the proposed maximum contaminant levels for either gross alpha particle activity or man-made radioactivity. Those levels are intended as preventative limits rather than as corrective limits.

Public Water Systems Requiring Radium Analysis: The monitoring requirements for the radium maximum contaminant level provide for an initial screening measurement of gross alpha particle activity to determine if analysis for radium-226 is needed. EPA requested comment on the number and location of community water systems that would exceed the proposed screening level of 2 pCi/l. A number of comments were received on the possible impact of the proposed screening level. The principal concern expressed was that a 2 pCi/liter screening level was unnecessarily low and would force a large number of public water systems to conduct expensive radium analyses in cases where the radium limit was not being exceeded.

A number of commentors were under the impression that radium daughter products were in equilibrium with radium in drinking water so that their accompanying alpha particle activity would be an indication of radium. Monitoring data from many public water systems indicates that because of differences in solubility and geological processes, the alpha particle activity is frequently much lower than would be observed for an equilibrium mixture of radium and daughter products and sometimes may be no greater than that due to radium-226 alone.

EPA agrees that in many cases adequate protection can be obtained with a screening level higher than 2 pCi/liter provided that the precision of the measurement is great enough to insure that the gross alpha activity is unlikely to exceed 5 pCi/l. The regulations have been amended accordingly. The effect of this change is that a screening test, in lieu of radium analysis, is permitted for most systems having gross alpha particle activities as high as 4 pCi/l. However, as noted in the Statement of Basis and Purpose for the proposed radionuclide regulations, care should be taken in evaluating the results of the screening test because the alpha particle activity screen does not measure radium-228, a beta emitter. For this reason, EPA recommends that, in localities where radium-228 may be present in significant quantities, the State establish a screening level no greater than 2 pCi/liter.

Costs and Technology for Radium Removal: One comment on radium removal costs stated that the EPA cost estimates may be too high because new technologies for radium removal are being developed. Another comment stated that the EPA estimates appear "reasonable at this time," and a third that the estimates are "too general" in that system size was not considered.

As discussed in the Statement of Basis and Purpose for the proposed radionuclides regulations, costs for radium removal were found to be essentially independent of system size for systems treating less than three million gallons per day. Since there are no data indicating that the maximum contaminant level for radium is being exceeded in systems larger than this, the EPA cost estimates are valid.

Three commentors thought the cost projections for radium removal might be low because disposal of radium wastes was not considered. The Agency is presently conducting a research study to investigate disposal costs. Compared to industrial effluents containing radium, the amount of radium involved is quite small. The only available data indicate that a commercial waste disposal service for radioactive materials would be expected to cost about 50 cents annually per person served for radium disposal. However, costs will vary depending on locality and the disposal method used. It should also be noted that any radium disposal problems generated by the proposed regulations will not be unlike those already encountered by the many communities already removing radium as part of their water softening processing.

Other comments suggested consideration of occupational exposure to radium in water treatment plants. The Agency has made a limited examination of the levels of radiation in the vicinity of ion exchange units used to remove radium in operating water treatment plants. Exposure levels to operating personnel are measurable and occupational exposures could range up to 25-100 mrem/yr. These doses are well below the Federal occupational guides for radiation workers of 5000 mrem/yr. Appropriate Federal Radiation Guidance will be provided if future studies indicate the problem of occupational exposure to treatment plant personnel is serious.

One commentor questioned the efficiency of radium removal by ion exchange used in the cost analysis in Appendix V of the Statement of Basis and Purpose. That analysis shows that treatment cost is relatively independent of radium removal efficiency as long as removal exceeds 90 percent. Operating data from currently used municipal water treatment systems indicate that average radium removal efficiency throughout the exchange cycle ranges from 93 to 97 percent.

Aggregate Dose Level: As noted in the preamble to the proposed radionuclides regulations, 40 FR 34325, EPA considered but rejected the use of an aggregate dose level in establishing maximum contaminant levels. This approach would consider both the risk to individuals and the total risk to the population served, so that the maximum contaminant level would be inversely related, within lim-

its, to the size of the exposed population group. Comments on the concept of aggregate dose levels overwhelmingly endorsed EPA's decision not to use that approach in the development of maximum levels under the Safe Drinking Water Act.

Maximum Contaminant Level for Radium: A number of States submitted comments on EPA's proposal to establish the maximum contaminant level for radium at 5 pCI/liter. One State suggested that a limit of 10 pCI/liter be established for small public water systems. This suggestion has not been accepted by EPA because the legislative history of the Safe Drinking Water Act indicates that, to the extent possible, all persons served by public water systems should be protected by the same maximum contaminant levels. A number of other States expressed concurrence in the 5 pCi/liter limit.

One commentor cited the results of a U.S. Public Health Service study that indicated that persons in communities with water having a concentration of 4.7 pCi/liter had a higher mortality incidence due to bone sarcoma than persons in communities with water having less than 1 pCi/liter. The commentor contended that the USPHS study did not show a significant difference in cancer risk at a 95 percent confidence level, and that in any event the number of excess cancers was significantly less than would be predicted on the basis of the NAS–BEIR Report.

EPA notes that the confidence level of the USPHS study was 92 percent which is not significantly different from a 95 percent criterion considering the overall precision of the USPHS study. Mortality estimates on which the 5 pCi/liter limit was based included all cancers, not just bone sarcoma. Moreover, the EPA estimates are for lifetime exposures, whereas most of the participants in the USPHS study were exposed for a substantially shorter period of time. Moreover, the incidence of cancer observed in the USPHS study is somewhat greater than would be predicted by the linear dose response model used by EPA, not less as suggested by the commentor. Given these facts it is EPA's view that the USPHS study supports its use of risk estimates from ingested radium as a valid measure of the impact of various control levels. EPA will, however, study new cancer incidence data as they become available to determine whether the 5 pCi/liter level provides appropriate protection.

Changes Made in the Proposed Regulations:

In response to comments received on the proposed regulations, a number of changes have been made. The comments and changes are discussed in some detail in Appendix A. The following list summarizes changes which have been made:

1. Section 141.2 has been revised to simplify the definitions of "gross alpha particle activity" and "gross beta particle activity." As proposed these definitions were confusing because they sought to make distinctions which were more properly set forth in §§ 141.15 and 141.16.

2. Section 141.15 has been changed to make clear that the maximum contaminant level for gross alpha particle activity does not apply to isotopes of uranium and radon.

3. Section 141.16 has been redrafted for clarity and provisions relating to the means of determining compliance have been moved to § 141.26. It should be noted that the average annual concentration of strontium-90 yielding 4 mrem per year to bone marrow is 8 pCi/1 not 2 pCi/1 as was stated in the Proposed Regulations. Accordingly, Table A in Section 141.16 has been corrected and the detection limit for strontium-90 listed in Table B, § 141.25 has been changed to 2pCi/1.

4. Section 141.25 has been revised to include newer analytical methods and to delete some obsolescent methods. The definition of detection limit has been changed to indicate clearly that it applies only to uncertainty in the precision of the measurement due to counting errors. Also, a new detection limit of 4 pCi/liter has been established for gross beta particle activity so that gross beta analysis may be substituted for strontium-89 and cesium-134 analyses in some cases. It should be noted that under § 141.27 the State, with the concurrence of the Administrator, may authorize the use of alternative analytical methods having the same precision and accuracy as those listed in §§ 141.25 and 141.26.

5. Section 141.26 has been redrafted for clarity and the alpha particle activity screening level has been redefined to provide a higher gross alpha screening limit as long as the precision of measurement insures that the gross alpha activity is unlikely to exceed 5 pCi/1. Also, the requirement for quarterly sampling has been revised to permit a yearly sample where a one-year record based on quarterly sampling has indicated the average annual gross alpha particle activity and radium-226 activity to be less than half the applicable maximum contaminant level. The period allowed for initial monitoring has been extended to three years rather than two years after the effective date of these regulations. Also, rather than require that subsequent monitoring be every three years for ground water and every five years for surface water, monitoring for both ground water and surface water will be required every four years.

6. Section 141.26 has been amended to provide that, when ordered by the State, a community water system will be required to participate in a watershed monitoring program for man-made radioactivity. EPA recommends that States require such programs in each principal watershed under their jurisdiction. In addition, the provision allowing the use of discharge data from nuclear facilities in lieu of special monitoring for man-made radioactivity has been amended to allow only the use of environmental surveillance data taken in conjunction with the State. Also in § 141.26 a screening level for gross beta particle activity has been established to reduce the cost of monitoring water systems affected by nuclear facilities.

If any screening levels for gross beta particle activity are exceeded, identification of specific radionuclides is mandatory prior to public notification and initiation of any enforcement action. In addition to the gross beta particle activity measurement, it may be necessary, as new energy technologies become available in the future, to monitor for specific man-made contaminants other than those currently identified. The Act provides that these regulations may be amended from time to time.

EFFECTIVE DATE

Section 1412(a)(3) of the Act provides that "The interim primary regulations first promulgated * * * shall take effect eighteen months after the date of their promulgation." The interim primary regulations first promulgated were those for microbiological, chemical and physical contaminants. They were promulgated on December 24, 1975, and will become effective June 24, 1977. Because it is desirable that all of the basic interim primary drinking water regulations take effect on the same date, and in view of the long lead time provided to public water systems for compliance with these radionuclide regulations, the radionuclide regulations also will become effective on June 24, 1977.

It is hereby certified that the economic and inflationary impacts of these regulations have been carefully evaluated in accordance with Executive Order 11821, and it has been determined that an Inflation Impact Statement is not required. (The estimated ten million dollar annual cost is less than the one-hundred million dollar annual cost cut-off established as the minimum for which an Inflation Impact Statement is required.)

For the reasons given above, Part 141, Chapter 40 of the Code of Federal Regulations is hereby amended as follows:

RUSSELL TRAIN,
Administrator.

JUNE 28, 1976.

1. By revising § 141.2 to include the following new paragraphs (j) through (o):

§ 141.2 Definitions.

* * * * *

(j) "Dose equivalent" means the product of the absorbed dose from ionizing radiation and such factors as account for differences in biological effectiveness due to the type of radiation and its distribution in the body as specified by the International Commission on Radiological Units and Measurements (ICRU).

(k) "Rem" means the unit of dose equivalent from ionizing radiation to the total body or any internal organ or organ system. A "millirem (mrem)" is 1/1000 of a rem.

(l) "Picocurie (pCi)" means that quantity of radioactive material producing 2.22 nuclear transformations per minute.

(m) "Gross alpha particle activity" means the total radioactivity due to

alpha particle emission as inferred from measurements on a dry sample.

(n) "Man-made beta particle and photon emitters" means all radionuclides emitting beta particles and/or photons listed in Maximum Permissible Body Burdens and Maximum Permissible Concentration of Radionuclides in Air or Water for Occupational Exposure, NBS Handbook 69, except the daughter products of thorium-232, uranium-235 and uranium-238.

(o) "Gross beta particle activity" means the total radioactivity due to beta particle emission as inferred from measurements on a dry sample.

2. By adding §§ 141.15, 141.16, 141.25 and 141.26 as follows:

§ 141.15 Maximum contaminant levels for radium-226, radium-228, and gross alpha particle radioactivity in community water systems.

The following are the maximum contaminant levels for radium-226, radium-228, and gross alpha particle radioactivity:

(a) Combined radium-226 and radium-228—5 pCi/1.

(b) Gross alpha particle activity (including radium-226 but excluding radon and uranium)—15 pCi/1.

§ 141.16 Maximum contaminant levels for beta particle and photon radioactivity from man-made radionuclides in community water systems.

(a) The average annual concentration of beta particle and photon radioactivity from man-made radionuclides in drinking water shall not produce an annual dose equivalent to the total body or any internal organ greater than 4 millirem/year.

(b) Except for the radionuclides listed in Table A, the concentration of man-made radionuclides causing 4 mrem total body or organ dose equivalents shall be calculated on the basis of a 2 liter per day drinking water intake using the 168 hour data listed in *"Maximum Permissible Body Burdens and Maximum Permissible Concentration of Radionuclides in Air or Water for Occupational Exposure,"* NBS Handbook 69 as amended August 1963, U.S. Department of Commerce. If two or more radionuclides are present, the sum of their annual dose equivalent to the total body or to any organ shall not exceed 4 millirem/year.

TABLE A.—*Average annual concentrations assumed to produce a total body or organ dose of ¼ mrem/yr*

Radionuclide	Critical organ	pCi per liter
Tritium	Total body	20,000
Strontium-90	Bone marrow	8

§ 141.25 Analytical Methods for Radioactivity.

(a) The methods specified in *Interim Radiochemical Methodology for Drinking Water*, Environmental Monitoring and Support Laboratory, EPA-600/4-75-008, USEPA, Cincinnati, Ohio 45268, or those listed below, are to be used to determine compliance with §§ 141.15 and 141.16 (radioactivity) except in cases where alternative methods have been approved in accordance with § 141.27.

(1) Gross Alpha and Beta—Method 302 "Gross Alpha and Beta Radioactivity in Water" *Standard Methods for the Examination of Water and Wastewater*, 13th Edition, American Public Health Association, New York, N.Y., 1971.

(2) Total Radium—Method 304 "Radium in Water by Precipitation" Ibid.

(3) Radium-226—Method 305 "Radium-226 by Radon in Water" Ibid.

(4) Strontium-89,90 — Method 303 "Total Strontium and Strontium-90 in Water" Ibid.

(5) Tritium—Method 306 "Tritium in Water" Ibid.

(6) Cesium-134 — ASTM D-2459 "Gamma Spectrometry in Water," *1975 Annual Book of ASTM Standards, Water and Atmospheric Analysis*, Part 31, American Society for Testing and Materials, Philadelphia, PA. (1975).

(7) Uranium—ASTM D-2907 "Microquantities of Uranium in Water by Fluorometry," Ibid.

(b) When the identification and measurement of radionuclides other than those listed in paragraph (a) is required, the following references are to be used, except in cases where alternative methods have been approved in accordance with § 141.27.

(1) *Procedures for Radiochemical Analysis of Nuclear Reactor Aqueous Solutions*, H. L. Krieger and S. Gold, EPA-R4-73-014. USEPA, Cincinnati, Ohio, May 1973.

(2) *HASL Procedure Manual*, Edited by John H. Harley. HASL 300, ERDA Health and Safety Laboratory, New York, N.Y., 1973.

(c) For the purpose of monitoring radioactivity concentrations in drinking water, the required sensitivity of the radioanalysis is defined in terms of a detection limit. The detection limit shall be that concentration which can be counted with a precision of plus or minus 100 percent at the 95 percent confidence level (1.96σ where σ is the standard deviation of the net counting rate of the sample).

(1) To determine compliance with § 141.15 (a) the detection limit shall not exceed 1 pCi/l. To determine compliance with § 141.15(b) the detection limit shall not exceed 3 pCi/l.

(2) To determine compliance with § 141.16 the detection limits shall not exceed the concentrations listed in Table B.

TABLE B.—DETECTION LIMITS FOR MAN-MADE BETA PARTICLE AND PHOTON EMITTERS

Radionuclide	*Detection limit*
Tritium	1,000 pCi/l.
Strontium-89	10 pCi/l.
Strontium-90	2 pCi/l.
Iodine-131	1 pCi/l.
Cesium-134	10 pCi/l.
Gross beta	4 pCi/l.
Other radionuclides	1/10 of the applicable limit.

(d) To judge compliance with the maximum contaminant levels listed in sections 141.15 and 141.16, averages of data shall be used and shall be rounded to the same number of significant figures as the maximum contaminant level for the substance in question.

§ 141.26 Monitoring Frequency for Radioactivity in Community Water Systems.

(a) Monitoring requirements for gross alpha particle activity, radium-226 and radium-228.

(1) Initial sampling to determine compliance with § 141.15 shall begin within two years of the effective date of these regulations and the analysis shall be completed within three years of the effective date of these regulations. Compliance shall be based on the analysis of an annual composite of four consecutive quarterly samples or the average of the analyses of four samples obtained at quarterly intervals.

(i) A gross alpha particle activity measurement may be substituted for the required radium-226 and radium-228 analysis *Provided*, That the measured gross alpha particle activity does not exceed 5 pCi/1 at a confidence level of 95 percent (1.65σ where σ is the standard deviation of the net counting rate of the sample). In localities where radium-228 may be present in drinking water, it is recommended that the State require radium-226 and/or radium-228 analyses when the gross alpha particle activity exceeds 2 pCi/1.

(ii) When the gross alpha particle activity exceeds 5 pCi/1, the same or an equivalent sample shall be analyzed for radium-226. If the concentration of radium-226 exceeds 3 pCi/1 the same or an equivalent sample shall be analyzed for radium-228.

(2) For the initial analysis required by paragraph (a)(1), data acquired within one year prior to the effective date of this part may be substituted at the discretion of the State.

(3) Suppliers of water shall monitor at least once every four years following the procedure required by paragraph (a)(1). At the discretion of the State, when an annual record taken in conformance with paragraph (a)(1) has established that the average annual concentration is less than half the maximum contaminant levels established by § 141.15, analysis of a single sample may be substituted for the quarterly sampling procedure required by paragraph (a)(1).

(i) More frequent monitoring shall be conducted when ordered by the State in the vicinity of mining or other operations which may contribute alpha particle radioactivity to either surface or ground water sources of drinking water.

(ii) A supplier of water shall monitor in conformance with paragraph (a)(1) within one year of the introduction of a new water source for a community water system. More frequent monitoring shall be conducted when ordered by the State in the event of possible contamination or when changes in the distribution system or treatment processing occur which may increase the concentration of radioactivity in finished water.

(iii) A community water system using two or more sources having different con-

centrations of radioactivity shall monitor source water, in addition to water from a free-flowing tap, when ordered by the State.

(iv) Monitoring for compliance with 141.15 after the initial period need not include radium-228 *except when* required by the State, *Provided*, That the average annual concentration of radium-228 has been assayed at least once using the quarterly sampling procedure required by paragraph (a)(1).

(v) Suppliers of water shall conduct annual monitoring of any community water system in which the radium-226 concentration exceeds 3 pCi/1, when ordered by the State.

(4) If the average annual maximum contaminant level for gross alpha particle activity or total radium as set forth in § 141.15 is exceeded, the supplier of a community water system shall give notice to the State pursuant to § 141.31 and notify the public as required by § 141.32. Monitoring at quarterly intervals shall be continued until the annual average concentration no longer exceeds the maximum contaminant level or until a monitoring schedule as a condition to a variance, exemption or enforcement action shall become effective.

(b) Monitoring requirements for man-made radioactivity in community water systems.

(1) Within two years of the effective date of this part, systems using surface water sources and serving more than 100,000 persons and such other community water systems as are designated by the State shall be monitored for compliance with § 141.16 by analysis of a composite of four consecutive quarterly samples or analysis of four quarterly samples. Compliance with § 141.16 may be assumed without further analysis if the average annual concentration of gross beta particle activity is less than 50 pCi/1 and if the average annual concentrations of tritium and strontium-90 are less than those listed in Table A, *Provided*, That if both radionuclides are present the sum of their annual dose equivalents to bone marrow shall not exceed 4 millirem/year.

(i) If the gross beta particle activity exceeds 50 pCi/1, an analysis of the sample must be performed to identify the major radioactive constituents present and the appropriate organ and total body doses shall be calculated to determine compliance with § 141.16.

(ii) Suppliers of water shall conduct additional monitoring, as ordered by the State, to determine the concentration of man-made radioactivity in principal watersheds designated by the State.

(iii) At the discretion of the State, suppliers of water utilizing only ground waters may be required to monitor for man-made radioactivity.

(2) For the initial analysis required by paragraph (b)(1) data acquired within one year prior to the effective date of this part may be substituted at the discretion of the State.

(3) After the initial analysis required by paragraph (b)(1) suppliers of water shall monitor at least every four years following the procedure given in paragraph (b)(1).

(4) Within two years of the effective date of these regulations the supplier of any community water system designated by the State as utilizing waters contaminated by effluents from nuclear facilities shall initiate quarterly monitoring for gross beta particle and iodine-131 radioactivity and annual monitoring for strontium-90 and tritium.

(i) Quarterly monitoring for gross beta particle activity shall be based on the analysis of monthly samples or the analysis of a composite of three monthly samples. The former is recommended. If the gross beta particle activity in a sample exceeds 15 pCi/1, the same or an equivalent sample shall be analyzed for strontium-89 and cesium-134. If the gross beta particle activity exceeds 50 pCi/1, an analysis of the sample must be performed to identify the major radioactive constituents present and the appropriate organ and total body doses shall be calculated to determine compliance with § 141.16.

(ii) For iodine-131, a composite of five consecutive daily samples shall be analyzed once each quarter. As ordered by the State, more frequent monitoring shall be conducted when iodine-131 is identified in the finished water.

(iii) Annual monitoring for strontium-90 and tritium shall be conducted by means of the analysis of a composite of four consecutive quarterly samples or analysis of four quarterly samples. The latter procedure is recommended.

(iv) The State may allow the substitution of environmental surveillance data taken in conjunction with a nuclear facility for direct monitoring of man-made radioactivity by the supplier of water where the State determines such data is applicable to a particular community water system.

(5) If the average annual maximum contaminant level for man-made radioactivity set forth in § 141.16 is exceeded, the operator of a community water system shall give notice to the State pursuant to § 141.31 and to the public as required by § 141.32. Monitoring at monthly intervals shall be continued until the concentration no longer exceeds the maximum contaminant level or until a monitoring schedule as a condition to a variance, exemption or enforcement action shall become effective.

APPENDIX A

RESPONSE TO PUBLIC COMMENTS

Proposed National Interim Primary Drinking Water Regulations for radionuclides, 40 FR 34324, were published for comment on August 14, 1975. Written comments on the proposed regulations were received, and a public hearing on the proposal was held in Washington on September 10, 1975. As a result of review of the written comments and of testimony at the public hearing, as well as further consideration of the available data by EPA, a number of changes have been made in the proposed regulations. The principal changes are summarized in the Preamble to the final regulations. The purpose of this Appendix is to discuss the comments received on various aspects of the proposed regulations, and to explain EPA's response to those comments.

Part I of the Appendix deals with comments on specific provisions of the proposed regulations, in numerical order. Part II concerns more general comments received by EPA. Responses to the five specific issues on which comments were solicited in the August 14 proposal are reviewed and discussed in the preamble to the promulgated regulations. Part III is the Agency's policy Statement of March 3, 1975, on the Relationship between radiation dose and effect.

PART I

Comments on Specific Provisions of the Proposed Regulations § 141.2—Definitions

A number of commentors stated that the definitions given in § 141.2 for gross beta particle and gross alpha particle activity were confusing because they excluded certain radionuclides. These definitions have been redrafted to omit the exclusions, which are more properly dealt with in the basic regulations.

§ 141.15—MAXIMUM CONTAMINANT LEVELS OF RADIUM-226, RADIUM-228, AND GROSS ALPHA PARTICLE RADIOACTIVITY

Several comments suggested that the maximum contaminant level for gross alpha particle activity should state clearly that this limit does not apply to isotopes of uranium and radon. This was the intention of the proposed regulations, and § 141.15 has been redrafted accordingly. Some commentors requested clarification of the impact of the exclusion of uranium and radon on monitoring procedures and compliance. It is true that the sample preparation techniques specified in § 141.25 preclude the measurement of the gaseous radionuclides radon-220 and radon-222. Their daughter products, however, will be retained in the sample as intended by these regulations. As noted in the Statement of Basis and Purpose, one of the main intentions of the maximum contaminant level for gross alpha particle activity is to limit the concentration of long half-life radium daughters. In cases where gross alpha particle activity exceeds 15 pCi per liter, analysis of the water for its uranium content by chemical or other means will be needed to determine compliance. Except in ground water impacted by uranium-bearing ores, such analyses will rarely be necessary.

Two commentors mentioned that no rationale for the gross alpha particle maximum contaminant limit of 15 pCi/1 was given in the preamble to the proposed regulations. The rationale for this limit is, however, discussed in the Statement of Basis and Purpose. It is based on a consideration of the radiotoxicity of other alpha particle emitting contaminants relative to radium. The 15 pCi/1 gross alpha particle limit, which includes radium-226 (but not uranium or radon), is based on the conservative assumption that if the radium concentration is 5 pCi/1 and the balance of the alpha particle activity is due to the next most radiotoxic alpha particle emitting chain starting with lead-210, the dose to bone will not be unduly increased. Though less precise than setting maximum contaminant levels for lead-210 specifically, the establishment of a limit on gross alpha particle activity is more in keeping with the current capability of State laboratories while providing significant public health protection. Reasons for omitting uranium and radon from the limit for gross alpha particle activity are given in the Statement of Basis and Purpose.

§141.16—MAXIMUM CONTAMINANT LEVELS OF BETA PARTICLE AND PHOTON RADIOACTIVITY FROM MAN-MADE RADIONUCLIDES

Several commentors had difficulty interpreting this section. It has been redrafted and that portion of the proposed maximum contaminant level for man-made radioactivity dealing with compliance has been moved to § 141.26 for purposes of clarity.

One commentor questioned the basis of the selection of the proposed 4 millirem annual limit. As stated in the preamble to the proposed regulations, the four millirem per year limit for man-made radioactivity was chosen on the basis of avoiding undesirable future contamination of public water supplies as a result of controllable human activities. Current levels of radioactivity in public water systems are below the proposed limit. Appropriate data on this point is provided in the Statement of Basis and Purpose.

Reference was made by one commentor to the Nuclear Regulatory Commission design criteria for light water reactors which limits the thyroid dose from a single nuclear reactor due to the liquid pathway to ten millirem per year. The commentor suggested that this number is in conflict with the proposed maximum contaminant level for man-made radioactivity. However, because the two levels are computed on different bases, iodine-131 concentrations meeting NRC design criteria would also meet maximum contaminant limits. Therefore, there is no conflict between these regulations and NRC design criteria. It should be noted, however, that the NRC limits are design criteria, not operational limits, and apply to only a single nuclear reactor. The EPA maximum contaminant limits have a completely different application. They apply to the finished waters served by a community water system which may use source waters contaminated by several reactors or other nuclear facilities.

Another commentor stated that the strontium-90 maximum contaminant level would produce a bone cancer dose of 4 millirem per year only after several decades of intake. That is correct—all of the maximum contaminant levels are based on an assumed lifetime ingestion at the concentration limits.

A few commentors stated that because in some localities the dose from strontium-90 in milk exceeds 4 mrem per year, the maximum contaminant level for strontium-90 in drinking water should be eliminated or made greater. The Administrator does not agree that the radioactive contamination of milk and milk products, which may occur in some localities, is a proper basis for relaxing maximum contaminant levels for drinking water. The maximum contaminant level for strontium-90 is not exceeded in community water systems at present nor is it likely to be exceeded in the foreseeable future. To permit unnecessary contamination of public water systems because of other environmental pathways impacting on man would be inappropriate.

A few commentors suggested that 2 liters per day was not an appropriate ingestion rate assumption for drinking water. The Administrator notes that a 2 liter per day intake is assumed for establishing maximum contaminant levels for all contaminants, not just radioactivity, and that this question has been discussed at length in the preamble and Appendix A to the National Interim Primary Drinking Water Regulations, 40 FR 59575.

A few commentors asked why potassium-40 was not considered as part of the maximum contaminant level for beta particle radioactivity. The amount of potassium in the body is controlled homostatically and is not proportional to water intake levels. Without the exception for potassium-40, some communities might be required to perform more analytical examination than necessary if waters exceeded the gross beta activity screening level. If the increased beta activity is due to potassium-40, there is no increased risk to users of the public water systems and therefore such tests are unnecessary.

§ 141.25—ANALYTICAL METHODS FOR RADIOACTIVITY

Several commentors noted that the Proposed Regulations on analytical methods did not allow for the substitution of equivalent alternative techniques. EPA agrees that this is an important consideration and § 141.27 has been added to the regulations to allow substitution of equivalent analytical methods with the approval of the State and the Administrator. Two commentors believed that no analytical methods should be specified as part of the regulations, 40 FR 34324. The Administrator believes, however, that defined analytical methods must be a part of the regulations so that compliance procedures are uniform and subject to verification.

Many commentors believed that alternative analytical methods were preferable to those listed in the proposed regulations and several made specific suggestions. EPA recognizes that some of the proposed analytical methods were obsolescent and for this reason a new handbook, *Interim Radiochemical Methodology for Drinking Water*, has been prepared by the Agency. § 141.25 has been revised to include these new methods and to delete some of the analytical methods proposed earlier. However, some Standard Methods have been retained because they are equivalent to the newer procedures and are currently being used by State laboratories.

Several comments concerned the need for laboratory certification and quality assurance. EPA will seek to certify at least one State laboratory in each State. The State may in turn certify additional laboratories. Pursuant to § 141.28, only monitoring results from laboratories approved or certified by the entity with primary enforcement responsibility will be acceptable.

Several comments were received concerning application of the defined detection limits. The detection limit requirements have been changed to indicate clearly that the limit applies only to uncertainty in the precision of the measurement due to counting errors. Other sources of imprecision and the overall accuracy of the determination are not a part of the detection limits given in this section but rather their control is to be implemented by means of the quality assurance program mentioned previously.

A few commentors believed that the proposed detection limit for gross alpha particle activity was too low. Because systems using very hard water may be unable to detect alpha particle activity at the 1 pCi/1 concentration, the detection limit for compliance with the gross alpha particle activity limit, § 141.15(b) has been increased to 3 pCi/1. This higher detection limit is not acceptable for gross alpha particle measurements substituted for radium analysis under § 141.26(a)(1)(i). If water hardness precludes use of this screening test, a radium analysis must be made to demonstrate compliance with § 141.15(1) of these regulations.

Most commentors believed the detection limits for man-made radioactivity were low but practicable in laboratories where modern testing facilities are available.

§ 141.26—MONITORING REQUIREMENTS FOR ALPHA PARTICLE AND RADIUM ACTIVITY

The major comments on § 141.26(a) were that the requirements were not clearly written and that the alpha particle activity screening test for a mandatory radium-226 measurement was too low thus necessitating unnecessary expense without increasing protection to the public health. Paragraph (a) has been redrafted to clarify the intent of these regulations; and, as discussed in the preamble to these regulations, the gross alpha particle screening level has been increased.

Some commentors objected to the requirement that quartely monitoring be continued when maximum contaminant levels are exceeded and others asked why quarterly sampling is needed. The reason why quarterly monitoring may provide additional public health protection where maximum contaminant levels are exceeded is discussed in the Statement of Basis and Purpose. The Agency agrees that quarterly sampling may be unnecessary in some cases and has amended the regulations to allow a single yearly sample where a one year historical record based on quarterly sampling shows the average annual gross alpha particle activity and the radium-226 activity to be less than one-half the applicable maximum contaminant levels.

Comments were divided on sampling frequency. Citizen groups tended to want more frequent monitoring and the States less frequent monitoring. Of particular public interest was the possible contamination of ground and surface water by mining operations. The revised regulations encourage the State to require more frequent monitoring for natural radioactivity in situations where mining or other operations may impact on water quality, when new sources of supply water are utilized or when water treatment processing is changed by the supplier of a community water system.

Several commentors requested an extension of the initial two-year period proposed for mandatory compliance. EPA is aware that these regulations call for a more expanded monitoring effort than is presently being carried out by most States. The regulations have been revised to require that initial monitoring begin within two years and that analysis be completed within three years of the effective data. In addition, the Agency has reconsidered, as suggested by several commentors, the proposed requirement that ground water be monitored every three years and surface water every five years and believes monitoring every four years for each is appropriate. The regulation has been so amended.

A few States requested that the initial monitoring of any community water system for radioactivity be at the discretion of the State and that the frequency of monitoring be determined by each State on a case by case basis. This is essentially the system now used. Congress has mandated *improved* control of drinking water quality, and these regulations seek to carry out that mandate.

Two commentors objected to the Agency's use of a gross alpha screening test to determine the need for radium-226 measurements because such a test is not applicable to radium-228, a beta emitter. Since radium-226 and radium-228 are not part of the same decay series, one of the commentors believed an evaluation which measures only gross alpha particle activity was inappropriate. It is true that radium-228 and radium-226 are in different decay series. However, the available monitoring data indicate that there is no record of radium-228 occurring in community water systems unless it is accompanied by radium-226. As pointed out in the Statement of Basis and Purpose, the radium-226 concentration in public water supply systems is almost always greater than the radium-228 concentration. Therefore, a screening test based on gross alpha particle activity is valuable for determining when further testing for specific radionuclides is

necessary. However, States are encouraged to require specific analyses for both radium-226 and radium-228 where radium-228 may be present.

Several commentors raised questions concerning the points at which samples are to be taken and the procedure to be followed where multiple, or alternate, sources are utilized. As indicated in both the Statement of Basis and Purpose, and § 141.2(c) of the Interim Primary Drinking Water Regulations, sampling is to be done at the "free-flowing outlet of the ultimate user." Where multiple sources are employed, the samples should represent an unbiased estimate of the maximum concentration of radionuclides ingested by persons served by the system.

The Administrator recognizes that in some communities several wells are used at different periods throughout the year to supply drinking water and that because of different concentrations of radioactivity in these wells the concentration in finished water may fluctuate considerably. It is recommended that in such cases the States require augmented sampling programs which include monitoring of source waters. In the revised regulations the State has been given authority to order such monitoring.

§ 141.26(b)—MONITORING REQUIREMENTS FOR MAN-MADE RADIOACTIVITY

There were two types of objection to the proposal that mandatory monitoring for man-made radioactivity be confined to systems serving more than 100,000 persons and systems impacted by nuclear facilities. Some commentors felt that all systems, including those utilizing ground water, should be monitored. Others believed that monitoring only systems serving large communities would not adequately reflect the situation in their States.

EPA believes that because of cost and the size and number of laboratories available now to do the radiochemical analysis required for man-made radioactivity, monitoring efforts are better directed at those systems which are most likely to be contaminated by man-made radioactivity. However, the State should require monitoring for man-made radioactivity in each principal watershed under its jurisdiction as necessary to determine the extent of radioactivity in surface waters. The regulations have been so amended.

Commentors representing consumers, States, and industry objected to the provision that discharge data from nuclear facilities could be used in lieu of monitoring for man-made radioactivity. This provision has been redrafted to reflect more adequately the intention of this provision. Suppliers may use data obtained through an environmental surveillance program conducted by a nuclear facility in conjunction with the State to show compliance with these regulations. In many cases these monitoring programs will include more complete and frequent analyses of radioactivity in source and finished waters than would normally be available through State efforts alone.

A few comments stated that the proposed monitoring for specific radionuclides in the vicinity of nuclear facilities would often be unnecessary and that if such tests could be preceded by a screening test for gross beta particle activity, monitoring costs would be reduced. EPA agrees with these comments as they apply to the required quarterly monitoring for strontium-89 and cesium-134. The regulations concerning monitoring in the vicinity of nuclear facilities have been amended to establish a screening level for gross beta particle activity of 15 pCi/l. Only if this concentration is exceeded is measurement of strontium-89 and cesium-134 required. Tritium and iodine-131 are not measured by a test for gross beta particle activity and the requirement for analyses for these radionuclides is retained.

Some commentors pointed out that monitoring for iodine-131 as proposed was unrealistic since a single "grab" sample per quarter might not detect intermittent discharges from nuclear facilities. Other commentors stated that the decay of iodine-131 would render any measurements meaningless. While there is merit in both arguments, continuous monitoring for iodine-131 is impractical in many cases because of cost considerations. However, monitoring for iodine-131 will be more meaningful if, each quarter, a sample based on five successive daily composites is measured, as required in the revised regulations. This measurement should be made as soon as possible after collection and appropriate decay corrections applied as outlined in *Interim Radiochemical Methodology for Drinking Water*, referenced in S141.25(a).

Several commentors requested supplemental information on the storage and analysis of composited quarterly samples. Additional comments questioned the feasibility of compositing quarterly samples for iodine-131 monitoring and the need to correct for decay between the time samples are collected and measured. The required treatment for the preservation of composited samples is discussed in both the Statement of Basis and Purpose and the reference cited above. In the case of iodine-131, hydrochloric rather than nitric acid should be used for acidification and sodium bisulfite should be added to the sample.

A few commentors requested that cesium-137 be included with cesium-134 in the monitoring program for man-made radioactivity. The Administrator believes, in the interest of cost, that only one cesium isotope measurement should be mandatory. Measurement of cesium-134, which provides more information on changes in environmental levels than cesium-137 monitoring, is preferable. However, States may include cesium-137 monitoring if they desire to do so. In many cases costs will not be affected significantly. When beta activity exceeds 50 pCi/l, identification of major radioactive constituents is required. The extent of such analysis should be based on the States' determination of what radionuclides are likely to be present in the water and the maximum dose that could be delivered by unidentified components.

A few commentors requested additional guidance on calculating the concentration of radioactivity yielding 4 mrem per year, based on NBS Handbook 69, as required by these Regulations. The Administrator anticipated this problem and the Agency is publishing a revised Statement of Basis and Purpose which includes a table giving the concentration that is calculated to result in a dose equivalent rate of 4 mrem per year from all radionuclides of interest. The revised Statement also contains other pertinent information needed to facilitate compliance with these regulations.

PART II

General Comments

Monitoring and treatment costs

Many comments were received on the Agency's estimate of monitoring costs under these proposed regulations. One State supplied cost estimates which were lower than analytical costs estimated in the preamble. Another State thought that cost estimates in the preamble "were about right." However, all other commentors thought that the cost estimates made by EPA were too low. There are several reasons for this difference of opinion. In some cases commentors provided an analysis of their estimated cost for compliance based on sampling frequencies in excess of those required by the proposed regulations and the use of additional test analyses not required by the regulations. Another source of difficulty was that, as stated in the preamble, the cost per sample did not include collection and shipping charges. One State estimated this cost as high as $15.00 per sample. No other examples were provided, however. This Agency's cost for obtaining one gallon water samples for its Eastern Environmental Radiation Facility in Alabama is, exclusive of labor costs: container cost, $.62; shipping empty, $1.00; return full container, $2.00. Since analyses for gross alpha particle activity and radium require less volume, States costs for most community water supplies should be lower.

A major source of disparity between Agency and commentor cost estimates was that the EPA estimates did not include capital equipment costs. This is particularly important for States having essentially no ongoing program for measuring radioactivity in water. In such cases the cost estimates will be exceeded if a new laboratory program must be established. In most cases, however, State laboratories are available with at least some equipment for initiating the required monitoring program.

Two states objected to the monitoring costs for natural radioactivity on the basis that they were not cost effective for small public water systems. They contended that monitoring should be restricted to large community water supplies. The Administrator believes that the requirements of the Safe Drinking Water Act are such that the quality of water served by community water supply systems should be independent of the population size to the extent feasible. It will be more expensive, in some cases, on a per person basis to monitor very small systems, but such costs are not impractical for even the smallest community water system. However, in the case of man-made radioactivity, the nature of the potential hazard, the availability of laboratory facilities and the cost of monitoring do justify limiting required monitoring to large community water systems, serving more than 100,000 persons, community systems impacted by nuclear facilities, systems using water from major watersheds, and such other systems as are designated by the State.

Other groups pointed out that on the whole the monitoring cost per person served is trivial and objected to the aggregation of national costs in the preamble. EPA believes that the national costs as well as the cost to individual community water systems, are worthy of consideration.

One commenter believed that the number of community water systems impacted by nuclear facilities had been underestimated because the number of nuclear facilities would increase markedly in the future and many community water systems would be impacted by a single nuclear facility. It is true that the number of nuclear facilities that will necessitate monitoring of community water systems will increase in the future. The cost estimates in the preamble were based on an assumed average of one and a half community water systems being impacted by each nuclear facility. The commenter believed two would be impacted by each nuclear facility in his State.

Another commentor wanted to know if all drinking water regardless of source would be monitored for both alpha particle and beta particle radioactivity. The Regulations are specific on this point. Systems utilizing only ground water need not monitor for man-made beta particle radioactivity. Sources using surface water must monitor for both beta and alpha particle activity if they serve more than 100,000 persons, utilize surface water which may be contaminated by effluents from nuclear facilities, or as required

by the State. Other surface water systems need not monitor for man-made radioactivity. However, it is recommended that all systems be monitored for gross beta particle activity.

A large number of respondents were concerned with the number and adequacy of existing monitoring facilities and the costs connected with establishing supplemental facilities. In some cases existing monitoring facilities may not be adequate. The situation will be more severe for those jurisdictions where the gross alpha particle concentration exceeds the screening level. However, the higher screen level in the revised regulation will reduce the number of mandatory radium analyses by a factor of two or more.

Moreover, the phased monitoring requirements imposed by these regulations should provide adequate time for State and private laboratories to add necessary facilities and equipment. It is true that many small systems will be required to monitor for gross alpha activity and, in the aggregate, bear the major cost impact of the monitoring requirements. However, it is precisely these systems which are most likely to be contaminated with natural radioactivity. There is no question but that additional funds will be required for such increased monitoring. It was the intent of Congress that these costs be borne by the individual public water systems and that corrective measures, such as consolidation of smaller systems, be employed to ameliorate this effect.

A few commentors questioned whether the proposed limits were "cost effective" in terms of both treatment and monitoring costs. As stated in the preamble to the proposed regulations, selection of an appropriate maximum contaminant level was not based solely on the estimated cost effectiveness of radium removal. As explained in the Statement of Basis and Purpose, the health risk estimates are uncertain by at least a factor of four. However, the difference in cost-effectiveness between different control levels is independent of this uncertainty and therefore provides information on where cost-benefit ratios become significantly poorer. The Statement of Basis and Purpose also examines why the cost-effectiveness of radium removal by ion exchange is low and suggests alternative approaches to obtaining maximum contaminant levels at lower costs. The cost-effectiveness of the required monitoring program will depend on the number of supplies identified as exceeding the maximum contaminant limits. This cannot be forecast until the initial monitoring is completed. In any event, a strict cost-effectiveness approach is not the intent of the Safe Drinking Water Act. Maximum contaminant levels are to prevent adverse health effects to the extent feasible.

One commentor interpreted a statement in the Preamble concerning future review of these regulations to indicate that the purpose of the Proposed Regulations was to conduct a national field survey for radioactivity in drinking water at State expense. A second comment expressed a similar opinion regarding monitoring requirements for man-made radioactivity.

The Proposed Regulations are based on the Administrator's determination that they protect health to the extent feasible after taking treatment costs into consideration. He is aware that the Agency's estimates of national cost are dependent on the number of community water systems impacted and that an adequate estimate of their number is not available now. By Congressional mandate these are interim regulations subject to revision in 1978. The Administrator would be remiss if he were to ignore new data on the impact of these regulations as it becomes available as an outgrowth of the reporting requirement.

Another commentor asked why the Agency had not set the limit for man-made radioactivity using a cost-benefit approach. The Agency does not believe such an approach is either practicable or needed at this time. Present levels of man-made radioactivity in community water systems are quite low—a statement supported in Appendix III of the Statement of Basis and Purpose and there is no evidence that allowing higher concentrations in drinking water would confer significant reductions in compliance costs. Effluent control costs are not likely to be changed by the proposed regulations for man-made radioactivity. Effluent control practices of the nuclear industry as currently regulated appear to be adequate in terms of the proposed maximum contaminant limits. The Agency does not believe it was the intention of Congress that the cost of removing man-made radioactivity from public water systems should be balanced against the cost of effluent controls required by regulations established under other legislation.

Calculational models used

One commentor objected to the statement in the preamble concerning the estimated dose due to drinking water contaminated by currently operating nuclear fuel cycle components. The objection was based on two points.

(1) That these estimates were based on calculational models, which may not accurately reflect reality.

(2) That the estimates do not consider aerial depositions from radioactive materials which are initially deposited into air and then fall out onto the ground and are washed into waterways.

The Administrator believes the best calculational models currently available were used for these estimates. Measurement of the actual doses is, of course, impossible at these low levels. As stated in the Statement of Basis and Purpose, the Administrator will consider new models as they are proposed by appropriate organizations and modify the proposed regulations as necessary to reflect new information as it becomes available. By basing compliance with maximum contaminant levels on measured concentrations of radioactivity in finished drinking water the Administrator believes aerial deposition as a source of water contamination is adequately considered.

Public water systems impacted

One commentor stated that the monitoring data included in the Statement of Basis and Purpose for community water systems were not representative of the radium or alpha particle radioactivity in sections of the country having abnormally high concentrations of natural radioactivity and therefore EPA's estimates of the impact of the proposed regulations were unrealistic. The Agency believes that the data given in the Appendix to the Statement of Basis and Purpose were representative of the country as a whole, but agrees there are sections of the country which routinely have higher amounts of radium in their community water systems. However, as stated in the Statement of Basis and Purpose, these national data were not used as a basis for the EPA estimate of the number of public water systems impacted by the proposed maximum contaminant limit for radium. Rather, that estimate is based on other monitoring data obtained mostly in regions where significant amounts of radium are commonly found in community water systems, as referenced in the Statement.

Linear nonthreshold response functions

One commentor stated the Agency was too conservative in the estimation of possible health effects because a linear nonthreshold dose response function was assumed. Another commentor stated a linear nonthreshold relationship is not conservative enough since an increased radiocarcinogenic response has been associated with low dose rates from alpha particle irradiation. Conversely, one commentor stated that there is a threshold for radiation injury from ingested radium and that the maximum contaminant level for radium should be based on his value for a threshold dose. Reasons for using a linear nonthreshold dose response were given in full in the Statement of Basis and Purpose and are reproduced here as Part III of this Appendix. The Agency is aware that one study on the results of clinical treatments with radium-224 indicates that protraction of the alpha exposure is more carcinogenic and that it has been hypothesized that lung cancer may be associated with very low dose rates from alpha particle emitters. Also, analyses of the radium dial painter data have been interpreted as indicating that bone cancers from lower radium doses occur later in life than from large doses and this has been interpreted as an argument for an effective threshold. However, the United States Public Health Service has studied this question in some detail, BRH/DBE 70–5, and EPA agrees with the USPHS finding that the data are insufficient to specify an unequivocal dose response model and their conclusion that, "* * * in the low dose region expected to be experienced by the general public, the assumption of a linear nonthreshold model continues to be a prudent public health philosophy for standards setting."

MISCELLANEOUS

Two States requested a definition of "nuclear facility." As explained in the Statement of Basis and Purpose, the term "nuclear facility" is flexible so that the States may determine which community water systems require additional monitoring. The term "nuclear facility" should not be construed as applying only to nuclear electric-generating plants and other components in the uranium fuel cycle but may also include, at the option of the State, waste storage areas, experimental facilities, and medical centers as outlined in the Statement of Basis and Purpose.

Four commentors believed that the proposed regulations would be difficult for persons working in community water systems to understand—that they were too technical. EPA agrees this is a highly technical subject not amenable to lay terms. However, the Agency has attempted to clarify the regulations and believes that all States have radiological health personnel who are willing to assist a supplier of water if particular problems of interpretation arise.

Several commentors expressed the opinion that data collected prior to implementation of the proposed regulations should be admissible as evidence of compliance. EPA agrees and the regulations have been modified so that analytical data acquired one year prior to the effective date of these regulations may be substituted for monitoring required during the initial period at the discretion of the State. This should reduce initial monitoring costs.

Two commentors expressed concern about adverse health effects that might occur as a result of sodium addition to water during the zeolite softening process. Possible health effects from sodium were considered in detail by the Agency in the development of the proposed regulations for inorganic chemicals, as well as for radium, and are discussed in the Statement of Basis and Purpose. The

Agency believes it not appropriate to set a maximum contaminant level for sodium. The consensus of opinion among medical personnel in this field is that, while the sodium added is not negligible, patients on a restricted, but noncritical, sodium diet would not be adversely affected at the increased levels contemplated. Patients for whom the increased levels might be critical are not normally permitted to use regular drinking water supplies but are restricted to specially processed water. The Statement of Basis and Purpose recommends that community physicians having patients in areas where the concentration of sodium is increased due to radium removal be so informed by the supplier.

One commentor took exception to the suggestion in the preamble that, taken as a whole, releases from hospitals and other industrial facilities would result in doses comparable to those released from nuclear facilities such as light water reactors. The statement in the preamble was not based on a full scale technical evaluation. The Agency is studying releases of radioactive materials from hospitals and other complexes through contractor research and will amend this estimate as necessary based on these and other findings.

Several respondents were in doubt as to the responsibilities of the water supplier in terms of actual performance of the required analyses. Allied questions were directed to whether the supplier of water or the State is responsible for the cost of analyses.

It is the intent of the regulations that the individual water supplier, while responsible for compliance with the regulations, may reasonably be expected to collect and transmit water samples to approved laboratories for actual performance of the radioanalysis. It is the intent of both Congress and these regulations that the principal costs associated with compliance with the Safe Drinking Water Act be borne by the individual public water systems. However, a State is not barred from analyzing samples for public water systems without charge.

One commentor wanted to know if the proposed maximum contaminant levels for radioactivity in drinking water replaced Federal Radiation Council Guidance on Radiation Protection Guides for the general population. These regulations do not replace FRC recomendations on the transient intake of radioactive materials, which included both the food and water pathways, and which contemplated, except in the case of radium, exposures of less than a lifetime duration. EPA believes that the FRC Range II limit for large population groups cannot be applied to a single pathway, such as drinking water, since FRC Guides include exposure from external radiation, inhaled radioactivity and radioactivity in food as well as drinking water.

Three commentors questioned basing the maximum contaminant limits on the same dose limit whether applied to any internal organ or to the whole body. EPA has considered this question with care in developing these regulations, recognizing that the conservatism of the maximum contaminant limits was increased by this decision. The decision not to consider critical organs for the ingestion of radioactivity in drinking water is based on the National Committee on Radiation Protection (NCRP) recommendations contained in NCRP Report No. 39. In that report, the NCRP recommended that organ dose limits for the general population be based on whole body dose and not at a fraction of the corresponding *occupational dose limit* for critical organs. The NCRP decision was in part based on the lack of data available at that time to consider appropriately the risk from a radiation insult to various organs. Such data are becoming available now and the International Commission on Radiation Protection (ICRP) is considering basing dose limits on the risk to various organ systems. When the ICRP recommendations are developed in final form they will be considered by EPA.

PART III

ORP Policy Statement on the Relationship Between Radiation Dose and Effect; March 3, 1975

The actions taken by the Environmental Protection Agency to protect public health and the environment require that the impacts of contaminants in the environment or released into the environment be prudently examined. When these contaminants are radioactive materials and ionizing radiation, the most important impacts are those ultimately affecting human health. Therefore, the Agency believes that the public interest is best served by the Agency providing its best scientific estimates of such impacts in terms of potential ill health.

To provide such estimates, it is necessary that judgments be made which related the presence of ionizing radiation or radioactive materials in the environment, i.e., potential exposure, to the intake of radioactive materials in the body, to the absorption of energy from the ionizing radiation of different qualities, and finally to the potential effects on human health. In many situations the levels of ionizing radiation or radioactive materials in the environment may be measured directly, but the determination of resultant radiation doses to humans and their susceptible tissues is generally derived from pathway and metabolic models and calculations of energy absorbed. It is also necessary to formulate the relationship between radiation dose and effects; relationships derived primarily from human epidemiological studies but also reflective of extensive research utilizing animals and other biological systems.

Although much is known about radiation dose-effect relationships at high levels of dose, a great deal of uncertainty exists when high level dose-effect relationships are extrapolated to lower levels of dose, particularly when given at low dose rates. These uncertainties in the relationships between dose received and effect produced are recognized to relate, among many factors, to differences in quality and type of radiation, total dose, dose distribution, dose rate, and radiosensitivity, including repair mechanisms, sex, variations in age, organ, and state of health. These fatcors involve complex mechanisms of interaction among biological chemical, and physical systems, the study of which is part of the continuing endeavor to acquire new scientific knowledge.

Because of these many uncertainties, it is necessary to rely upon the considered judgments of experts on the biological effects of ionizing radiation. These findings are well-documented in publications by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the National Academy of Sciences (NAS), and the National Council on Radiation Protection and Measurements (NCRP), and have been used by the Agency in formulating a policy on relationship between radiation dose and effect.

It is the present policy of the Environmental Protection Agency to assume a linear, nonthreshold relationship between the magnitude of the radiation dose received at environmental levels of exposure and ill health produced as a means to estimate the potential health impact of actions it takes in developing radiation protection as expressed in criteria, guides, or standards. This policy is adopted in conformity with the generally accepted assumption that there is some potential ill health attributable to any exposure to ionizing radiation and that the magnitude of this potential ill health directly proportional to the magnitude of the dose received.

In adopting this general policy, the Agency recognizes the inherent uncertainties that exist in estimating health impact at the low levels of exposure and exposure rates expected to be present in the environment due to human activities, and that at these levels the actual health impact will not be distinguishable from natural occurrences of ill health, either statistically or in the forms of ill health present. Also, at these very low levels, meaningful epidemiological studies to prove or disprove this relationship are difficult, if not practically impossible to conduct. However, whenever new information is forthcoming, this policy will be reviewed and updated as necessary.

It is to be emphasized that this policy has been established for the purpose of estimating the potential human health impact of Agency actions regarding radiation protection, and that such estimates do not necessarily constitute identifiable health consequences. Further, the Agency implementation of this policy to estimate potential human health effects presupposes the premise that, for the same dose, potential radiation effects in other constituents of the biosphere will be no greater. It is generally accepted that such constituents are not more radiosensitive than humans. The Agency believes the policy to be a prudent one.

In estimating potential health effects it is important to recognize that the exposures to be usually experienced by the public will be annual doses that are small fractions of natural background radiation to at most a few times this level. Within the U.S. the natural background radiation dose equivalent varies geographically between 40 to 300 mrem per year. Over such a relatively small range of dose, any deviations from dose-effect linearity would not be expected to significantly affect actions taken by the Agency, unless a dose-effect threshold exists.

While the utilization of a linear, nonthreshold relationship is useful as a generally applicable policy for assessment of radiation effects, it is also EPA's policy in specific situations to utilize the best available detailed scientific knowledge in estimating health impact when such information is available for specific types of radiation, conditions of exposure, and recipients of the exposure. In such situations, estimates may or may not be based on the assumptions of linearity and a nonthreshold dose. In any case, the assumptions will be stated explicitly in any EPA radiation protection actions.

The linear hypothesis by itself precludes the development of acceptable levels of risk based solely on health considerations. Therefore, in establishing radiation protection positions, the Agency will weigh not only the health impact, but also social, economic and other considerations associated with the activities addressed.

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